



AUG 8 2003 Application Number 09/708,276

8642/94

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Gary J. Nabel & Elizabeth G. Nabel)
Serial No. : 09/708,276) Examiner : William O. Sandals
Filing Date: November 7, 2000) Group Art Unit No.: 1636
For : METHOD FOR TREATING)
PROLIFERATIVE DISEASE WITH)
p27 AND FUSION THEREOF.)

DECLARATION UNDER 37 C.F.R. § 1.131

The Commissioner of Patents and Trademarks
Washington, D.C. 20231

SIR:

We, Gary J. Nabel and Elizabeth G. Nabel, declare as follows:

1. That we are the inventors of the subject matter claimed in the above-identified U.S. Patent application.

2. Prior to August 22, 1996, we completed the invention described in the claims at issue in the above-identified U.S. patent application, as evidenced by the following facts:

3. Prior to August 22, 1996, while in the course of research and experimentation at the University of Michigan, Ann Arbor, MI, we prepared and characterized a METHOD FOR TREATING PROLIFERATIVE DISEASE WITH p27 AND FUSIONS THEREOF according to the following procedure evidenced by the enclosed pages of the NIH Grant Application "CKIs and Control of Vascular Smooth Muscle Cell Cycle" ("NIH Grant Application.")

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4. These pages describe experiments showing an upregulation of p21 and p27 in a time pattern that is inversely correlated with vascular smooth muscle cell proliferation (page 31).

5. We also conceived of the construction of plasmid expression vectors encoding human p27 (page 30) and delivery of those vectors into blood vessels using a catheter delivery system (page 49).

6. We worked diligently to reduce the above invention to practice from the conception date until the filing date of the above-identified U.S. patent application.

7. Each of the dates deleted from the enclosed pages of the NIH Grant Application is prior to August 22, 1996.

8. We declare that all statements made of our own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above applications or any patent granted thereon.

8/6/03

Date

Gary J. Nabel

Gary J. Nabel

8/6/03

Date

Elizabeth G. Nabel

Elizabeth G. Nabel